DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 123, 126, 141, 149 -152 and 159 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 123, 126, 141, 149 -152 and 159 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheiner et al. (US 6,415,183 B1) in view of Park (US Patent Publication 20030153954 A1).

5. Scheiner et al. discloses a diaphragmic pacing system that monitors patient respiratory activity and delivers an electrical stimulus to the phrenic nerve. “Tip electrode 121 and ring electrode 122 can be used for sensing respiratory activity by a method such as minute ventilation… and/or for delivering diaphragm therapy by delivering an electric stimulus to phrenic nerve 102”(col. 3, lines 39-44). The electrodes sense respiratory activity and thus sense “respiration”.

6. As depicted in figure 4, “in block 404, the present method analyzes whether the diaphragm responded to the therapy delivered in block 303. This can be done by analyzing the signal representing respiratory activity shortly after the therapy is delivered. If it is determined in block 404 that the diaphragm did not respond to the therapy, then the voltage pulse level is increased in block 405. The method illustrated in FIG. 4 delivers the stimulation pulse at a predetermined frequency unless the input signal indicates that the minute ventilation is above a predetermined level. The electric stimulus is delivered by the output circuit via the lead to the electrode to the phrenic nerve” (col. 7, lines 49-60). Therefore, the stimulation parameter (i.e. voltage) is “incrementally adjusted until the breathing cycle is further adjusted to reach the desired level". Furthermore, since the minute ventilation is increased to a desired level, the “inspiration duration" and “inspiration volume” also be increased.

7. Scheiner et al. monitors for threshold change to determine Cheyne-Stokes respiration (col. 7, lines 16-18). Scheiner et al. discloses the device substantially as claimed but does not specifically recite the creation of an “intrinsic baseline profile”. Park et al. teaches the use of a baseline respiration comparison to determine if Cheyne-Stokes respiration is occurring in a patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the determination of Cheyne-Stokes respiration as disclosed by Scheiner, with the baseline comparison for determining Cheyne-Stokes respiration as disclosed by Park et al. since such a modification would provide the predictable results of enabling a medical technician to monitor the progression of the patient and confirm the presence of Cheyne-Stokes

respiration. By having a baseline visually displayed a physician or technician can observe and confirm the diagnostic assessment.

8. As to claim 141, since the device provides stimulation to increase the minute ventilation and provide respiratory therapy to the patient, the stimulation elicits an inspiration rate different from the inspiration rate (i.e., increases from intrinsic respiration until a threshold value is met).

9. As to claim 149, Scheiner et al. discloses the treatment of patients with Cheyne-Stokes respiration. Cheyne-Stokes respiration is a pattern of breathing with gradual increase in depth and sometimes in rate to a maximum, followed by a decrease resulting in apnea. Since Scheiner et al. provides stimulation therapy and treatment for patients with Cheyne-Stokes respiration (i.e. breathing with increased depth and rate), Scheiner obviously provides stimulation to "elicit a slow elongated inspiration" in order to counter the Cheyne-Stokes respiration of increased depth and rate.

10. As to claim 151, “the exact pulse level/threshold for stimulation of the phrenic nerve is determined during implantation, and it is desired to keep the level as low as possible to save batter power and provide patient comfort” (col. 7, lines 1-5). Therefore the stimulation delivered by Scheiner et al. is “low level sequential stimulation” in order to preserve battery power.

11. As to claim 152, providing stimulation to enhance the patient’s respiration will obviously manipulate blood gases.

12. As to claim 159, as depicted in Scheiner et al. figure 4, once the breathing reaches a desired level, stimulation is ceased and the system returns to monitoring respiration.

13. As to claim 150, the modified Scheiner et al. discloses the device substantially as claimed but does not explicitly disclose delivering stimulation to "elicit a fast, short inspiration". It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation to enable the patient to execute fast, short inspiration in order to provide the predictable results of modifying the stimulation treatment to meet specific patient therapeutic needs and requirements to mitigate a variety of breathing disorders such as hypoventilation.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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